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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Campbell et al.
Serial No.: 08/499,423
Filed : July 7, 1995
Title : Interior Liner for Tubes, Pipes and Blood Conduits

Conf. No.: 2478
Art Unit : 3738
Examiner: Brian E. Pellegrino

MS AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF JAMES D. LEWIS, Ph.D.

1. I have been employed with W.L. Gore & Associates for 31 years. For much of that time I have been involved with the development and manufacture of polytetrafluoroethylene vascular grafts. I am a named inventor on a number of patents directed to vascular devices.

2. I am a named inventor of the present patent application (S.N. 08/499,423) and of U.S. Patent 5,628,782, which is the reference used in a 35 USC 102(e) rejection of claims 1, 3-7, 9, 10, 14-16, 19, 20, 23-26 and 28-30. I note that claim 1 is the only independent claim and therefore the question of patentability of this group of claims revolves primarily around the patentability of claim 1. As such, my comments below primarily address claim 1.

3. The Examiner has asserted that "the claimed physical property of the tube (in this case, a substantially unchanged second circumference upon expansion 100%) is present in the prior art material to some extent even though not

explicitly recited." With regard to the vascular graft described in U.S. Patent 5,628,782, the Examiner's assertion is entirely incorrect. It is well appreciated that a myriad of products, although made of substantially the same materials, can have entirely different functional capabilities as a result of engineering the application of the materials for the intended use. W.L. Gore & Associates has commercialized a vascular graft intended for dialysis applications under the name Diastat® that is marked under U.S. Patent 5,628,782. Neither this commercial product nor any of the examples described in this patent will provide, as required by claim 1 of the present application, the initial diametrical distensibility (at least 100%) and subsequent resistance to further dilatation if used within a designed range of operating pressures. A product conventionally labeled as a commercial "Vascular Graft" is by necessity resistant to dilatation from fluid pressure. Great effort is expended during design and manufacture of these grafts to make them resistant to dilatation. If not, these polymeric prosthetics are vulnerable to failure by aneurysmal rupture from exposure to blood pressure over time. They are labeled according to their nominal internal diameter and typically sold in diametric increments of 1 or 2mms. It is considered entirely unacceptable for a graft designated as a 6mm diameter graft to dilitate to 7mm in use, and certainly not to 8mm. As such, any prosthetic tube designated as a "Vascular Graft" is not distendable due to internal pressure in amounts anything like 100%.

The vascular grafts described in U.S. Patent 5,628,782, based primarily on commercial GORE-TEX™ Vascular Grafts (as noted at col. 11, lines 36-42), are entirely resistant to dilatation from fluid pressure, being designed to maintain the specified nominal internal diameter (e.g., 6mm) for the lifetime of a patient. As such, they do not dilitate 100% or more in normal use, and accordingly cannot anticipate claim 1 of the present patent application. Attempting to dilate these grafts under exposure to high pressures ultimately results in failure by rupture before a 100% diameter increase has occurred.

4. I have also reviewed U.S. Patent 5,061,276 to Tu et al., in view of the rejection of claims 1, 5, 9, 10, 14, 17, 19, 20, 22-26, and 28-31 under 37 U.S.C. §102(b). This patent teaches (from the abstract and col. 3, lines 8-12) the construction of a vascular graft "with one or more layers of polytetrafluoroethylene and/or a polyfluoroethylene-elastomer blend, and a layer of an elastomer with the elastomer being in the form of a coating or fiber", with the intent of providing a graft having increased elasticity. I note that (according to Tu et al. at col. 5, lines 46-48) the elastic fibers, applied under tension, will minimize dilatation of the graft. My comments above with regard to the unacceptability of substantial diametric dilatation of vascular grafts under pressure also apply here. I also note that at col. 13, lines 15-26 this patent describes the compliance of examples of the graft construction taught by Tu et al. and the compliance of a commercial GORE-TEX Vascular Graft. I have not measured compliance of any of these grafts but do not see any reason to dispute the compliance values provided in the Tu et al. patent. These compliance values, ranging from 1.0×10^{-2}%/mmHg for the GORE-TEX graft up to 5.2×10^{-2}%/mmHg for the most compliant graft according to Tu et al., do not suggest that any of these tubular grafts will provide, as required by claim 1 of the present application, initial diametrical distensibility (at least 100%) under the application of internal pressure and subsequent resistance to further dilatation if used within a designed range of operating pressures.

5. It is my opinion that the teachings of neither Myers et al. (U.S. Patent 5,628,782) nor Tu et al. (U.S. Patent 5,061,276) anticipate claim 1 of the present patent application.

James D. Lewis, Ph.D.

October 21, 2010

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